REMARKS

FORMAL MATTERS

Claims 38-49 are pending after entry of the amendments set forth herein.

Claim 27 is amended. Support for this amendment is found in the claim as previously presented and in the specification at, for example, page 23, line 24 to page 29, line 11.

New claims 38-49 are added. Support for these new claims is found in, for example, the claims as originally filed and throughout the specification at, for example, page 23, line 24 to page 29, line 11; page 14, lines 6-20; and page 16, lines 6; page 28, line 21 to page 29, line 11.

Applicant respectfully requests reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

REJECTIONS UNDER §103(A)

Claims 27-37 were variously rejected under §103(a). These rejections are addressed in more detail below.

Pratt in view of Dardik - Claims 27-32 and 34

Claims 27-32 and 34 were rejected under §103(a) as being unpatentable over Pratt (Laryngoscope 1986 96(6):625-9; 29th Ann. Meeting of Amer Society for Head and Neck Surgery) in view of Dardik (US 3,974,526). This rejection is respectfully traversed.

As set out in MPEP §2143, in order to establish a prima facie case of obviousness, three basic criteria must be met.

1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
2) There must be a reasonable expectation of success.
3) The prior art reference, or references when combined, must teach or suggest all the claim limitations.

All three criteria must be met. If any one of these three criteria is not met, a prima facie case of obviousness has not been established.

Pratt discloses studies in rabbits using freeze-dried arterial allografts made from femoral or brachial arteries. The Office pointed in particular to the following statement in Pratt:

> With the limitations of the present study notwithstanding, this new microvascular technique shows promise. Eventually, it is anticipated that freeze-dried placental or donor vessels could be used in clinical trials if future preliminary laboratory studies in rabbits and larger animals are successful.

The Office asserted that Pratt and Chow show that freeze dried tissues prevent immune response. However, Pratt does not use vessels from either umbilical cord or placenta in the allografts.

The Office attempts to fill this gap with the Dardik reference. Dardik discloses use of placental and umbilical tissues as a source for vessels for grafts. However, Dardik also teaches that these vessels should be chemically treated (i.e., tanned) to remove surface antigens thereby reducing antigenicity.

As Applicant understands it, the Office has concluded that since Dardik showed that chemically treated umbilical and placental vessels can be used as grafts, and that Pratt shows that freeze-drying reduces antigenicity, then it would be obvious to use the vessels from placental or umbilical tissues as taught by Dardik in the free-drying process of Pratt to arrive at the claimed allografts.

Applicant respectfully submits that the Office has failed to establish a *prima facie* case of obviousness for failure to meet at least one of the three required criteria set out above – namely, reasonable expectation of success.

As evidence in support of the arguments made in this amendment, applicants have filed with this amendment a Declaration by James R. Schneider 37 C.F.R. §1.132 ("Schneider Declaration"). The Schneider Declaration provides evidence that preserved vessels prepared by freeze-drying human placental or umbilical cord vessels maintain sufficient integrity for use as grafts, and further can withstand pressure similar to that found in an adult.

First, vessels of human placenta and umbilical cord are quite delicate. For example, the umbilical cord vessels are surrounded by a protective sheath of tissue so as to prevent damage or collapse of the vessels. Until the experiment was actually done, one could not predict whether removal of umbilical cord or placental vessels followed by freeze-drying would so badly damage the vessels to render them useless. The freeze-drying process could very well have destroyed the integrity of the vessels. (Schneider Declaration, paragraph 6).

Second, in nature, vessels of human placenta and umbilical cord are only subjected to fetal blood pressure. Fetal blood pressure is usually in the range of about 60/25 mmHg. In contrast, blood pressure in a healthy adult is about 140/80 mm Hg. Thus the placental and umbilical cord vessels in nature are subjected to less than about *half* of the pressure to which adult vessels are subjected. Moreover, blood pressure in adults with hypertension or malignant hypertension (those who would likely receive an endovascular graft) is even higher – about 160/90 and 180/120, respectively. As discussed above, one could not predict whether the integrity of the placental or umbilical cord vessels would be maintained after freeze-drying. Similarly, there was no reasonable expectation that *freeze-dried* vessels could be used in an adult graft and withstand *at least twice or more the blood pressure* than that to which the fresh tissue is subjected in nature. (Schneider Declaration, paragraph 7)

Moreover, applicant notes that the Pratt reference is co-authored by the present inventor, James Schneider. As stated by Dr. Schneider, the Pratt reference, at best, only makes a wish as to the use of placental vessels. (Schneider Declaration, paragraphs 9 and 10). Further, this wishful statement is far from one that inspires confidence of success. Pratt's statement, again, speaks for itself:

> Eventually, it is anticipated that freeze-dried placental or donor vessels could be used in clinical trials *if future preliminary laboratory studies in rabbits and larger animals are successful.*

(emphasis added)

Finally, Dr. Schneider has provided evidence of unexpected results in his declaration submitted herewith. As discussed above, many uncertainties existed as to whether freeze-dried human umbilical cord or human placental vessels of the present invention would maintain integrity when subjected to blood pressure of a human adult (120/80 mmHg). Surprisingly, not only did freeze-dried vessels maintain integrity with no aneurysm formation or vessel wall rupture when subjected to blood pressure of a human adult, the freeze-dried vessels also maintained integrity when subjected to abnormally high blood pressure, e.g., a blood pressure associated with human hypertension (160/120 mmHg). (Schneider Declaration, paragraphs 12-18)

In view of the arguments above, withdrawal of this rejection is respectfully requested.

Pratt and Dardik in view of Lau and Chin - Claims 33 and 35-37

Claims 33 and 35-37 were rejected under §103(a) as being unpatentable over Pratt and Dardik, and further in view of Lau (US 5,876,432) and Chin (US 5,800,540). This rejection is respectfully traversed.

The failure of the combined disclosures of Pratt and Dardik to render the claimed invention obvious is discussed above, and applies to claims 33 and 35-37 with equal force.

Combining Lau and/or Chin with Pratt and Dardik does not cure the deficiencies of the rejection. Lau and Chin at best only disclose particular types of stents.

Withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SNDR-001CIP.

Respectfully submitted,
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Date: Feb 1, 2005

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